Appendix C. Recruitment Script

When called by a potential subject, please make introductions and answer any questions that the volunteer may have concerning the study. If the potential subject is still interested, please read the following statement:

Thank you for calling about information on volunteering to participate in "A Phase 1, Randomized, Open-label, Single-center Study of TDENV-PIV and LAV Dengue Vaccine Platforms as part of a Heterologous Prime-boost Strategy in Healthy Adults in a Non-Endemic Region"

We appreciate your interest. I will provide you some information that will help you determine if you can participate in the study.

Alternatively, the information below can be emailed to potential subjects:

I would like to share some information with you regarding an upcoming clinical trial entitled:

A Phase 1, Randomized, Open-label, Single-center Study of TDENV-PIV and LAV Dengue Vaccine Platforms as part of a Heterologous Prime-boost Strategy in Healthy Adults in a Non-Endemic Region.

Background:

This study involves two experimental dengue vaccines. Dengue is a common infection affecting travelers to many areas of the world, including Southeast Asia, Central America, South America, and the Caribbean. It is caused by a virus and is transmitted by a mosquito. Dengue can cause fever, tiredness, and even severe bleeding or death. It can pose a threat to military operations; therefore, the military is trying to develop a vaccine to protect against dengue.

This study will look at the effects of combining two experimental dengue vaccines. This is not the first time that either of these dengue vaccines will be used in humans, but it is the first time they will be used together. It will take place at a clinic-style research facility in Silver Spring, Maryland, and is sponsored by The Surgeon General, Department of the Army. The vaccines will be given in your shoulder using a needle, and blood samples will be collected to look at your body's response. The goals of this study are to determine if the vaccines are safe when used together and to see how your body responds to the vaccines. One of the vaccines is a live-attenuated, or weakened, vaccine, just like the chickenpox or measles vaccines. The other is an inactivated or killed vaccine, like the tetanus or hepatitis vaccines.

Duration:

This study will last either 8 or 13 months, including the time involved for screening, depending which experimental group you may be assigned to. One or two clinic visits are required to see if you qualify for the study. If you are accepted into the study, you will receive 1 dose of each of the vaccines. Half of the people will receive the vaccines 1 month apart, and half will receive the vaccines 6 months apart. Some people will get the live vaccine first, others will get the killed vaccine first. After each injection, there will be follow-up visits. These visits will continue for six months following the last vaccination in each

WRAIR
IRB
WRAIR # 2136 Approval expires 12 Aug 2015
Version 3.1 Signed HSPB
Earlier Versions Invalid

group. There will be a total of either 15 or 16 scheduled clinic visits (not including the initial screening).

Requirements and Restrictions:

You must meet certain requirements to participate in this study, which I am going to list for you. You don't have to respond, but you may ask questions if you want me to clarify any of the following requirements or restrictions:

- Subjects must be at least 18 and not older than 49 years of age at Visit 1.
- Subjects must be in good health and have no significant current or past diseases as established by a medical history and physical examination.
- Subjects must not have had received a previous experimental dengue vaccination prior to enrollment or plan to receive another flavivirus vaccine for the entire study duration.
- Active duty military members need a signed approval memo from their supervisor to participate
- Subjects must have a valid state or federally issued picture ID to access the Naval Medical Research Center and Walter Reed Army Institute of Research (WRAIR) in Silver Spring, be willing to attend all of the required visits over the next 8 or 13 months (including screening), and be willing to refrain from participation in any other clinical studies involving investigational drugs or vaccines while participating in this study.
- Subjects must agree to not become pregnant or breastfeed during the study and also be willing to use a reliable form of contraception during the study for safety reason, as the effects of these vaccines have not yet been studied in infants or unborn children.
- Subjects must not have donated or received blood, blood products, or plasma within 90 days prior to starting the study or plan on donating blood or plasma during the study.
- Subjects must be negative for hepatitis B and hepatitis C viruses, as well as HIV, as confirmed by laboratory testing.

There may be other reasons why you cannot participate in this study and those will be discussed at the screening visit.

Possible Risks:

There are risks associated with receiving this vaccine.

Based on experience with these and similar vaccines, mild reactions are expected to occur in some subjects. These generally include tenderness, redness, and mild swelling at the injection site. These reactions will most likely resolve on their own within a few days. You may also experience other reactions, such as headache, nausea, a low fever, rash, or mild flu-like symptoms. There may be some risks that are unknown. There is always a chance that someone may experience a severe allergic reaction, just as some people do to other vaccines

WRAIR # 2136 Approval expires 12 Aug 2015
Version 3.1 Signed HSPB
Earlier Versions Invalid
WRAIR IRB

or drugs, like penicillin. After each vaccination you will observed in the clinic for a short period of time.

After each vaccination you will see a physician in the clinic who will evaluate the number and type of reactions.

Compensation:

You will receive compensation for participating in this study. Civilians or off-duty military will be compensated a maximum of $2130:

- $50 for screening visit (1 total)
- $130 for visit with a blood draw (15-16 total)
- $25 for referring another volunteer into the study (Referral Bonus)

On-duty military personnel and federal employees will be compensated a maximum of $850:

- $50 for screening visit (1 total)
- $50 for visit with a blood draw (15-16 total)

Federal employees will be compensated at the same rate as active duty military subjects (in accordance with the Dual Compensation Act). However, federal employees and active duty military personnel are entitled to full compensation if the individual provides documentation of approved leave or the visit occurs outside of normal duty hours. Otherwise, these individuals will be compensated at the lesser "on-duty" rate above. Volunteers will not be compensated for unscheduled visits.

Can I schedule an appointment for you to be seen by the research staff so that you can make a decision about volunteering for the study?

WRAIR
IRB
WRAIR # 2136 Approval expires 12 Aug 2015
Version 3.1 Signed HSPB
Earlier Versions Invalid